This document is a translation of the complaint to the Ombudsman on September 27, 2024, concerning the introduction of the Seqirus H5N8 avian influenza vaccine in Finland in the summer of 2024

Complaint to the Ombudsman, September 27, 2024
Legality of the Authorities' Actions Concerning the Introduction of the Zoonotic H5N8 Influenza Vaccine Seqirus (Avian Influenza Vaccine)

Finland was, in the summer of 2024, the only country in the world whose health authorities recommended vaccination against the avian influenza virus (H5N8) with a vaccine that has not been tested on humans for a specific Finnish population group (https://thl.fi/en/topics/infectious-diseases-and-vaccinations/vaccines-a-to-z/avian-influenza-vaccine#who-is-the-avian-influenza-vaccine-given-to, accessed September 9, 2024). This decision has provoked disapproval. To our understanding, the H5N8 virus is not circulating globally; instead, the circulating virus is the H5N1 subtype, which causes only mild, transient symptoms in humans (see Annex 2), which can be successfully treated with medication. Currently, there are very few cases of avian influenza worldwide. For example, Tuija Gadd, a research professor at the Finnish Food Authority, stated in an article in Maaseudun Tulevaisuus on September 6, 2024, that the European Centre for Disease Prevention and Control had defined this year as an exceptionally quiet virus season since the 2019–2020 season ("Avian influenza has failed to appear this year, and the reason may be the immunity developed by gulls" - News - Maaseudun Tulevaisuus, accessed September 10, 2024).

Our criticism targets the illegal or, at the very least, deficient actions of the Finnish Institute for Health and Welfare (THL) and the Finnish Ministry of Social Affairs and Health (STM) regarding the process and introduction of the Seqirus avian influenza vaccine. The Seqirus vaccine, designed to protect against the H5N8 avian influenza virus subtype, has only been tested on ferrets. The lack of data from clinical trials conducted on humans raises concerns about the short- and long-term adverse effects of the vaccine on the lives and health of the Finnish population. The rapid introduction of the vaccine and deficiencies in communication prevent the realization of the principle of informed consent and undermine citizens' trust in the healthcare system and the reliability of the authorities' actions.

Endangering the health of Finns: THL may have endangered the lives and health of Finns by introducing a vaccine that has not been tested on humans, without comprehensive safety studies, such as a Phase IV immunogenicity and safety study, in a situation where there is currently no pandemic or similar condition in the world that would necessitate urgent vaccination measures.

Annex 1: Legal claims and questions, as well as violations of human rights conventions related to the decision by THL and STM to use the Zoonotic H5N8 Influenza Vaccine Seqirus without comprehensive evidence-based safety studies and adequate communication.
Annex 2: Medical background information and analysis supporting the legal considerations related to the grounds of the complaint. The medical background information and analysis in the annex are primarily compiled from international sources.
Annex 3: Scientific assessment of the article
https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2024.29.25.2400383
Annex 4: Response from Fimea (Finnish Medicines Agency) to an information request.
Annex 5: Contracts and reference discussions related to the matter THL/515/8.00.02/2018 / Purchase reservation agreement for a pandemic influenza vaccine (Response to information request from THL, June 19, 2024).
Annex 6: Information request to the EMA (European Medicines Agency) regarding the avian influenza vaccine, for which no acknowledgment of receipt has been received to date.